IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re Testosterone Replacement	**)**	
Therapy Products Liability Litigation	**)**	**Case No. 14 C 1748**
Coordinated Pretrial Proceedings	**)**	**MDL No. 2545**
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This document applies to all cases	**)**	
and to *Rowley v. AbbVie, Inc. et al.*,	**)**	
Case No. 15 C 2760	**)**	

CASE MANAGEMENT ORDER No. 123
(rulings on certain motions *in limine* in
***Rowley v. AbbVie Inc. et al.*, Case No. 15 C 2760)**

MATTHEW F. KENNELLY, District Judge:

Robert Rowley was prescribed AndroGel, a testosterone replacement therapy (TRT) drug, by physician assistant Teryl Hunsaker in April 2012. In April 2013, Rowley was diagnosed with a deep vein thrombosis (DVT) in his left leg. He alleges that AndroGel caused the DVT and has sued AbbVie, Inc. and Abbott Laboratories (collectively AbbVie), which make and sell the drug.

Rowley's case is the fifth AbbVie "bellwether" case in this multidistrict litigation proceeding to go to trial. In this order, the Court rules on certain of the parties' motions *in limine.* At the final pretrial conference set for May 31, 2018, the Court will hear argument on the remaining motions.

A. AbbVie's motions

1. Evidence about off-label marketing

AbbVie contends that Rowley was prescribed AndroGel on-label and that, as a

result, evidence about off-label marketing is irrelevant and should be excluded. Rowley contends that these marketing efforts affected PA Hunsaker's decision to prescribe the drug and are therefore relevant. The Court will hear argument on this point at the final pretrial conference.

2. Evidence of AbbVie's sales and profits from AndroGel

Rowley contends that evidence regarding the amount and growth of AbbVie's sales and profits from AndroGel is admissible to show its motive to expand the market for the drug beyond the allegedly narrow group of persons to whom the drug was approved for sale by the Food and Drug Administration (FDA). AbbVie argues this evidence is irrelevant because Rowley was prescribed the drug on-label. This motion is interrelated with the previous one; the Court will hear argument on the point at the final pretrial conference.

3. Causation opinions by Rowley's treating medical personnel

a. PA Teryl Hunsaker

AbbVie seeks to exclude opinion testimony regarding causation by PA Hunsaker, another PA named Brent Pitcher, and Dr. Douglas Hyldahl, Rowley's primary care physician. (Rowley has agreed not to offer opinion testimony by Dr. Daniel Sharp, which AbbVie had also moved to exclude.)

It appears that after being diagnosed with a DVT in April 2013, Rowley continued to take AndroGel. PA Hunsaker discontinued the prescription in June 2013, noting in his records that he was doing so because "I do believe that [Rowley's] androgel is a significant contributing factor to his development of dvt." AbbVie's attorneys questioned Hunsaker about this in detail during his deposition, and he fully explained the basis for

the notation and his decision to discontinue the prescription. Because Hunsaker formed this opinion during the course of his treatment of Rowley, no report under Federal Rule of Civil Procedure 26(a)(2)(B) was required as a prerequisite for admission of his testimony. *See Meyers v. Nat'l R.R. Passenger Corp.*, 619 F.3d 729, 734-35 (7th Cir. 2010). And though Rowley appears not to have disclosed Hunsaker under Rule 26(a)(2)(A) as a witness who would present opinion testimony, the non-disclosure was harmless because the opinion was disclosed in Hunsaker's treatment notes, and AbbVie had a full and fair opportunity to question him about it during his deposition. *See* Fed. R. Civ. P. 37(c)(1).

AbbVie also argues that Hunsaker's opinion is insufficiently supported and that, as a PA, he is not qualified to render an opinion on causation. The Court will hear argument on these points at the final pretrial conference.

b. PA Brent Pitcher

PA Brent Pitcher worked with Hunsaker. It appears from Pitcher's notes that he related to Rowley a message from Hunsaker related to Hunsaker's view that AndroGel was a significant contributing factor to Rowley's DVT. Assuming that Hunsaker's opinion is admissible, testimony by Pitcher on this point would be unnecessarily duplicative. The Court excludes it under Federal Rule of Evidence 403.

c. Dr. Douglas Hyldahl

Dr. Hyldahl, as indicated earlier, was Rowley's primary care physician. His notes from June 2013 reflect that he agreed with the recommendation to stop Rowley's use of AndroGel due to his DVT two months earlier. AbbVie's counsel questioned Dr. Hyldahl about this during his deposition, and he stated that "[a]s a general rule, in both men and

women, we avoid hormone replacement in individuals who have deep vein thrombosis" and that this is because "we would look at it as a possible contributing factor." He did not conclude that AndroGel caused the DVT, "[o]nly that it might have been a contributing factor." Pl.'s Resp. to Defs.' Mots. In Limine, Ex. V at 105-06. Contrary to AbbVie's contention, Dr. Hyldahl does appear to have formed this conclusion during and as a part of his care and treatment of Rowley, so as with PA Hunsaker, no report under Rule 26(a)(2)(B) was required. And as with Hunsaker, any non-disclosure of the fact that Dr. Hyldahl might render this opinion testimony was harmless, *see* Fed. R. Civ. P. 37(c)(1), because it was disclosed in his records and AbbVie had a full and fair opportunity to question him about his during his deposition. At the final pretrial conference, the Court will address AbbVie's contention that Dr. Hyldahl's testimony on this point is not sufficiently supported to be admissible.

4. Marketing materials not seen by Rowley's prescribing physicians

AbbVie has moved to bar evidence of its marketing of AndroGel to PA Hunsaker and Rowley. It relies on Rowley's testimony that he did not think he had ever seen an ad for AndroGel before he started taking it and that he did not rely on such advertising. AbbVie also relies on Hunsaker's testimony that he had prescribed AndroGel (to other patients) before being visited by an AbbVie sales representative who pitched him on the drug and that he could not recall whether the representative provided any information about the drug's risks and benefits. But as Rowley contends, and as the Court has ruled when this issue has been presented in previous bellwether trials, there is circumstantial evidence that would permit a reasonable jury to find that in prescribing AndroGel to Rowley, Hunsaker was influenced by the sales representative's efforts,

even if he does not now recall them.

The Court wishes to inquire further, however, regarding the purpose for which Rowley proposes to introduce this evidence. If this is related to the question of off-label marketing, it is likely that the admissibility of this evidence will rise or fall with the Court's ruling on the admission of off-label marketing evidence. If, however, Rowley intends to offer this on his claims of fraudulent or negligent misrepresentation, he will need to articulate to the Court what (if anything) in the sales representative's marketing pitches he contends was false or misleading. The Court will address this point with counsel at the May 31 final pretrial conference.

5. Adverse event reports evidence

The Court denies AbbVie's motion to bar evidence of adverse event reports (AERs). The Court has previously ruled that such evidence may be relied upon by an expert to support a causation opinion, even if it is not the strongest form of causation evidence that is available. And assuming for purposes of discussion that AERs are hearsay, an expert may rely on otherwise inadmissible evidence if it is reasonably relied upon by experts in the field, as the Court has previously ruled. Fed. R. Evid. 704. And the Court again concludes, as it has in connection with past trials, that the probative value of this evidence to the jury in weighing an expert's opinion substantially outweighs any prejudicial effect it may have, enabling Rowley to disclose the contents of the reports to the jury. *Id.*

The Court also notes that AERs regarding venous thromboembolic (VTE) events are admissible as evidence of notice to AbbVie, a non-hearsay purpose. The Court is unpersuaded by AbbVie's argument that to be admissible for this purpose, a particular

AER must involve a VTE event substantially similar to Rowley's—given, among other things, the similarity of the mechanisms involved in various types of VTE events. *See* Pl.'s Resp. to Defs.' Mots. In Limine at 20.

B. Rowley's motions

1. In limine rulings from prior trials

Rowley asks the Court to adopt *in limine* rulings made in connection with prior trials. It's unclear the request is even needed; the Court's pretrial rulings apply throughout the MDL unless otherwise noted at the time. In the Court's view, the onus is on a party contending that a ruling should be changed or does not apply given particular circumstances to seek reconsideration or a modification.

Several of the prior rulings identified by Rowley are fully applicable here, specifically points 1a (communications with the FDA regarding unbranded advertising); 1b (the FDA's 1996 webpage regarding Androderm); 1d (expert testimony from AbbVie corporate fact witnesses); 1e ("good company" conduct); 1f (circumstances surrounding plaintiff's retention of counsel); 1h (commentary about litigation abuse, tort reform, or the societal costs of litigation); 1i (emphasis on the plaintiff's state of residence); and 1j (AbbVie's responsibility for the acts of its predecessor entities).

With regard to point 1c (the Court's instruction regarding responsibility for a drug's label), AbbVie argues that the instruction given by the Court in prior trials runs afoul of Utah law, which applies in Rowley's case. In addition, with regard to point 1g (the plaintiff's use of other prescription drugs), AbbVie argues that Rowley's use of certain medications is relevant for reasons applicable to this case. The Court will hear argument on these points at the final pretrial conference.

2. Evidence / argument excluded by agreement

AbbVie has agreed not to present evidence or argument regarding Rowley's religious affiliation or beliefs; the timing of disclosure during discovery of a second DVT that Rowley had in 2016 or a sanction order relating to this; or the fact that AbbVie's trial counsel examined Rowley's expert Dr. Rinder in an unrelated case. Both parties have agreed not to reference the number of lawyers representing the other side. The Court adopts the parties' agreements on these points.

3. Evidence off-label marketing

As indicated earlier, the Court will hear argument at the final pretrial conference regarding the admissibility of evidence of off-label marketing by AbbVie.

4. IMS data that postdates Rowley's use of Androgel; Dr. Khera's opinions regarding post-2015 TRT prescribing trends

The Court adopts its prior rulings precluding evidence of TRT prescriptions postdating plaintiff's injury and testimony regarding prescribing trends after a post-injury label change, for the reasons discussed when the Court made those rulings.

5. Cumulative expert testimony

AbbVie reports that it intends to call one of its two general causation witnesses, Dr. Bierer or Dr. Marais, but not both. *See* Defs.' Resp. to Pl.'s Mots. In Limine at 15. AbbVie should be prepared to advise the Court and defense counsel at the final pretrial conference which of the two it intends to call. This will resolve the primary cumulativeness issue that has been the subject of prior rulings by the Court. Any additional issues regarding cumulativeness of defense expert testimony are to be

asserted by Rowley if and when it becomes appropriate to do so during trial.

MATTHEW F. KENNELLY
United States District Judge

Date: May 28, 2018